REMARKS

The amendments and remarks are in response to the final Office Action dated February 10, 2004. At the time of the Office Action, claims 1-32 were pending in this application. Claims 1-34 are now pending. This Response to Office Action is filed with a Request for Continued Examination and a Request for a Two (2) Month Retroactive Extension of Time. Authorization is given to charge fees namely, $595.00, to Deposit Account No. 50-0951 for the Extension of Time and for the additional claim fees not previously paid. Authorization is also given to charge any deficiencies or credit any over payments to Deposit Account No. 50-0951.

In the Office Action, the specification and claims 3-5, 10, 11, 15, 16, 19, 30 and 31 were objected to because of minor informalities. Claims 1, 2, 6-9, 12-14, 17, 18, 20-29 and 32 were rejected. The rejections are set out in more detail below.

I. Objections to Claims

Claims 9, 10, 18-21, 23 and 27 were objected to because of minor informalities. Appropriate amendments have been made and withdrawal of all of these objections is respectfully requested.

II. Rejection Under 35 U.S.C. §112 ¶(2)

Claims 9, 21, 24-27, and 32 were rejected under 35 U.S.C. §112 ¶(2). Appropriate amendments have been made and withdrawal of all of these rejections is respectfully requested.

III. Review of Claims

Prior to addressing the rejections on art, a brief review of a few claims of the present application is appropriate. Claim 1 is directed to a non-invasive blood pressure measurement method which requires keeping the wrist at a posture so as to lower the tendons to a position near the radial artery and cause the radial artery to be close to the radius. Claim 1 also requires applying a changing external pressure to the skin above a point where the radial artery crosses a most protuberant spot on a volar aspect of the radius of the wrist and detecting a pulse wave signal of the radial artery along with a change in said external pressure on the skin above said point.

Claim 17 is directed to a non-invasive blood pressure measuring apparatus, which includes a wrist holding device for keeping a patient's wrist at a posture that can lower a position of at least one tendon of the wrist near a radial artery to be measured, and cause the radial artery to be close to a radius of the wrist. Also included is a pressure bladder for applying an external pressure to the radial artery and a pressure bladder holding device for stably positioning said pressure bladder on the skin above a point where the radial artery crosses a most protuberant spot on a volar aspect of the radius of the wrist and a pressure feeding-measuring system. The pressure bladder also includes a compressing wall adapted to face the skin above the radial artery of the wrist. Further include is a pressure feeding-measuring system and a pulse transducer located on the skin above the point for detecting a pulse wave signal of the radial artery.

IV. Rejections Under 35 U.S.C. §103(a)

The Office Action rejected claims 1, 2, 6-8, 17, 21, and 23 under 35 U.S.C. §103(a) as being unpatentable over WO 97/12542 to Hon ("Hon '542") in view of U.S. Patent No. 5,840,037 to Tochikubo et al. ("Tochikubo"). Claims 1, 2, 6, 12, 14, 17, 21, 22, and 28 were also rejected under 5 U.S.C. §103(a) as being unpatentable over Hon in view of U.S. Patent No. 5,243,990 to Aung et al., ("Aung"). Additionally, the Office Action rejected claims 1, 2, 6, 7, 13, 14, 17, 18, 21, 23, and 29 under 35 U.S.C. §103(a) as being unpatentable over Hon '542 in view of U.S. Patent No. 4,869,261 to Penaz ("Penaz"). Further, claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over to Hon '542 in view of Tochikubo and in further view of United States Patent No. 6,132,383 to Chesney et al. ("Chesney"). Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hon '542 in view of Tochikubo and further in view of Chesney.

As Hon'542 appears to be main reference cited by the Office Action, a brief description is appropriate. In Hon '542, a wrist stabilizer is described that may cause the wrist to be flexed at any angle or no angle at all. Such a description indicates that Hon '542 did not understand that the flexing angle of wrist could affect the precision of blood pressure measurement. Accordingly, Hon '542 cannot be used to specify any optimal sites or angles for ensuring measurement precision and accuracy. Instead, Hon '542 aims to increase the

signal to noise ratio when measuring the blood pressure by an auscultaory method. To accomplish this goal, Hon '542 discusses changing the measuring position from the conventionally used upper arm to the wrist where the flesh is less fatty than the upper arm, adding a ring to isolate a portion of tissue to magnify the signal, reducing the volume of inflatable cuff, and using a wrist stabilizer to reduce noise created from arm movement. *See line 8 of page 6- line 2 of page 7.* Hon '542's description that the wrist stabilizer may have any angle means actually that Hon '542 just accepts a technical prejudice in conventional methods of blood pressure measurement, and does not newly teach or suggest any useful angle or location.

Further, none of the cited references appreciate the anatomical complexity of the wrist. Accordingly, none of the cited references teach or suggest a point where the radial artery crosses a most protuberant spot on a volar aspect of the radius of the wrist. Particularly, Hon '542 only mentions the radial artery and does not specify any advantageous position along the radial artery.

U.S. Patent to Hon et. al. 4,993,422 ("Hon'422"), which was provided in an Information Disclosure Statement, also fails to appreciate the anatomical complexities, and therefore also fails to teach or suggest the features recited in claims 1 and 17. Hon'422 only describes that the pressure transducer should placed over the radial artery of the patient proximate the joint of the wrist. *See col.5, lines 66-col.6, lines 4; col.6, lines 29-34; col.7, lines 63-64.* Such a non-particular description is only a general position and does not even consider the anatomical complexities of the wrist. Tochikubo is directed to measurements on the upper arm of patient. Further, Chesney merely mentions that a healthcare professional can palpate the wrist to determine where to apply the sensor. *See Figs. 1C. 2A, col.7, lines 10-13; col.8, lines 4-5.* Such a method can determine the positioning of the strongest pulse, which only determines the point having a shortest distance between the radial artery and the skin rather the point having a shortest distance between the radial artery and the radius. The position of the strongest pulse and the point where the radial artery crosses a most protuberant spot on a volar aspect of the radius of the wrist are usually different. Such

generalities clearly do not appreciate the anatomical relationship between the radial artery and the wrist as recited in claims 1 and 17.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. *See In re Young*, 927 F.2d 588, 591, 18 U.S.P.Q.2d 1089, 1091 (Fed. Cir. 1991) and *In re Keller*, 642 F.2d 413, 425, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981). Furthermore, the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Additionally, in supporting an obviousness rejection under 35 U.S.C. § 103, it is not permissible to use hindsight knowledge obtained from the Applicant's own disclosure as the suggestion for modifying the cited references to meet the limitations recited in the claims. *See, for example, W. L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In contrast to Hon '542, the main goal of the present application is to eliminate or reduce the influences of complicated anatomical structure of the wrist on the precision of wrist blood pressure measurement. As noted above, it is not appropriate to use the Applicant's own disclosure as the suggestion to support a rejection under 35 U.S.C. §103.

As discussed in a helpful telephone conversation with the Examiner, the claims have been amended to more clearly define the features that achieve the goal of the present application. Additionally, attachments are provided as an Appendix to this Response to Office Action to provide further illustration of the research related to the application. The attachments are merely illustrative of the principles involved and are for discussion purposes only.

In order to achieve the goal of the application, the Applicants investigated the change of displacement and distortion of different tissues in human wrist, and the change of the blood pressure value measured by conventional non-invasive methods, along with the change in the position of detailed measuring site on the wrist by performing Magnetic Resonance Imaging (MRI) and experiment of blood pressure measurement. MRI images of a wrist are illustrated at different positions. *See Appendix A*. Graphs of the affect of various positions of the wrist on the accuracy of blood pressure measurements are also provided. *See Appendix B*. Stress maps were calculated comparing the pressure transmission to radial artery at different positions by using finite element models built based on these MRI images. *See Appendices C_1-C_4*. The results indicated the position which can transmit accurately the external pressure to the radial artery is the most protuberant spot on the volar aspect of the radius (L_1), as recited in independent claims 1 and 17.

For example, for blood pressure measurements based on the oscillometric method, the experimental results indicated that the detailed site which can accurately measure the radial arterial blood pressure is the site S_0, where the radial artery crosses the most protuberant spot on the volar aspect of the radius (L_1). *See Appendix C_1-C_4 and lines 13-16 of page 4 of the present application*. Subsequent research concluded that the precision of the blood pressure measurement is sensitive to the measuring position, so that even small variations in position away from the most protuberant spot on the volar aspect of the distal end of the radius can result in differences in blood pressure measurement. As the references do not teach or suggest such a site, independent claims 1 and 17 are believed to be allowable.

The dependent claims are believed to be allowable due to their dependence from allowable independent claims and for further features recited therein. For instance, in addition to the specifying a point where the radial artery crosses a most protuberant spot on a volar aspect of the radius of the wrist, the accuracy and precision of the measurement can also be affected by other factors. The measured blood pressure will vary greatly when the wrist turns with the long axis of the forearm as the axis of rotation, or when the hand bends towards the palm side or the back side of the hand. *See Appendix A and lines 18-25 of page 4 of the present application.*

For example, the MRI images taken at the cross section passing S_0 and the blood pressure waveforms measured at S_0 show that, if the wrist flexing angles are kept within the range of 100-170 degrees, the tendons nearby the radial artery are lowered and the radial artery is caused to be close to the radius moderately, so that the blood pressure measured at by the apparatus are equal to actual blood pressure measured by standard invasive blood pressure measurement monitor. Nevertheless, if the wrist flexing angles are out of the range of 100-170 degrees, such a posture will either raise the tendons or distort the radial artery, and so that the actual blood pressure are over- or under-measured by our apparatus. *See Appendix C_1-C_4*. This example vividly shows that, in order to ensure the precision of wrist blood pressure measurement, the wrist flexing angle should be specific rather than discretional like that discussed by Hon '542 or other cited references.

V. Conclusion

Applicant has made every effort to present claims which distinguish over the cited references, and it is believed that all claims are in condition for allowance. Therefore, Applicant invites the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicant respectfully requests reconsideration and prompt allowance of the pending claims.

Respectfully submitted,

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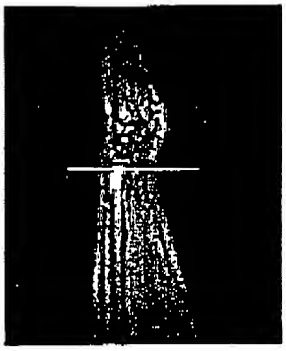
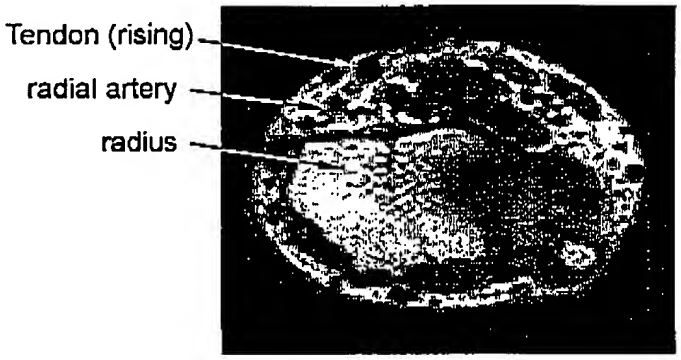
APPENDIX A

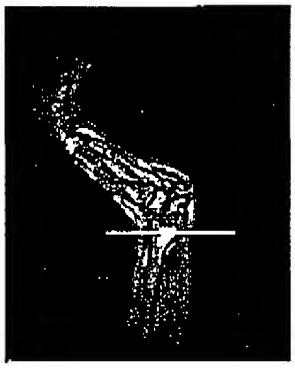
INFLUENCE OF WRIST FLEXING ANGLE ON DISPLACEMENT AND DISTORTION OF DIFFERENT TISSUES (MRI Image)

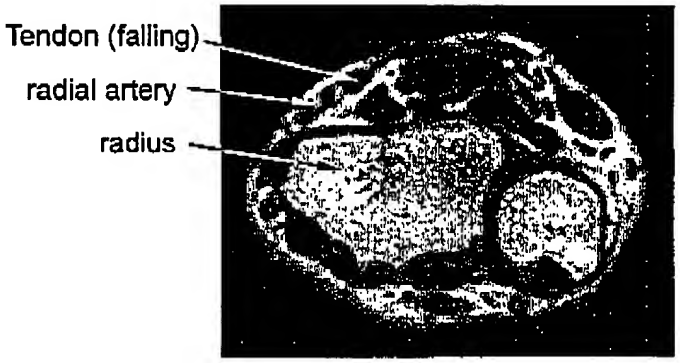
wrist flexing angle > 170°





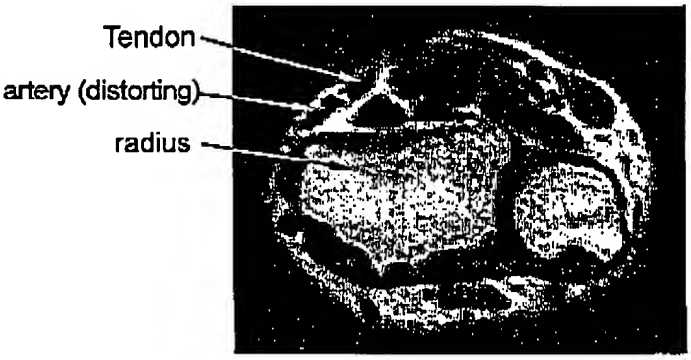
100° <wrist flexing angle < 170°



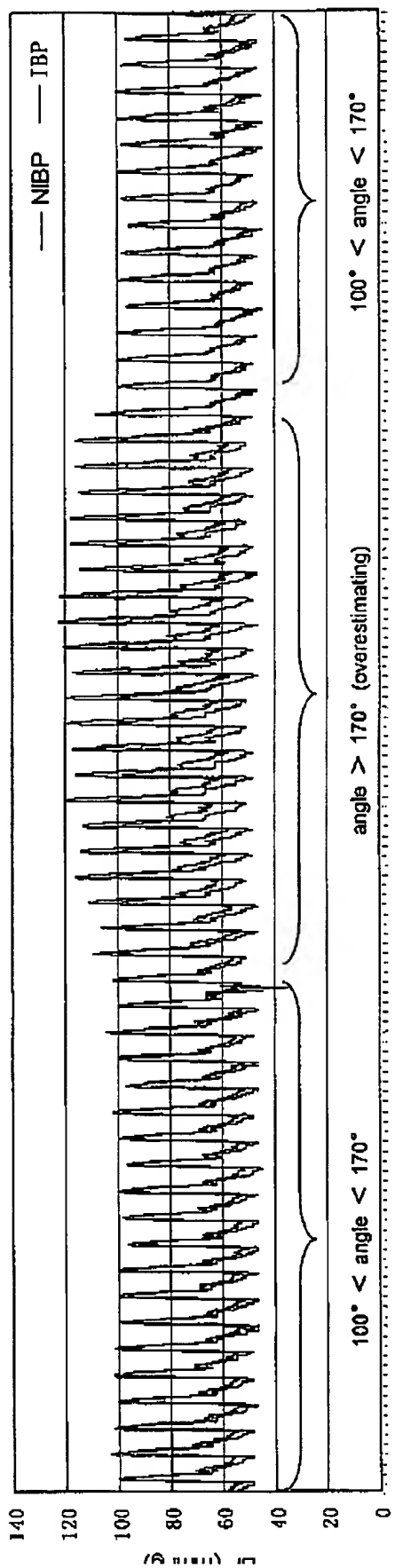


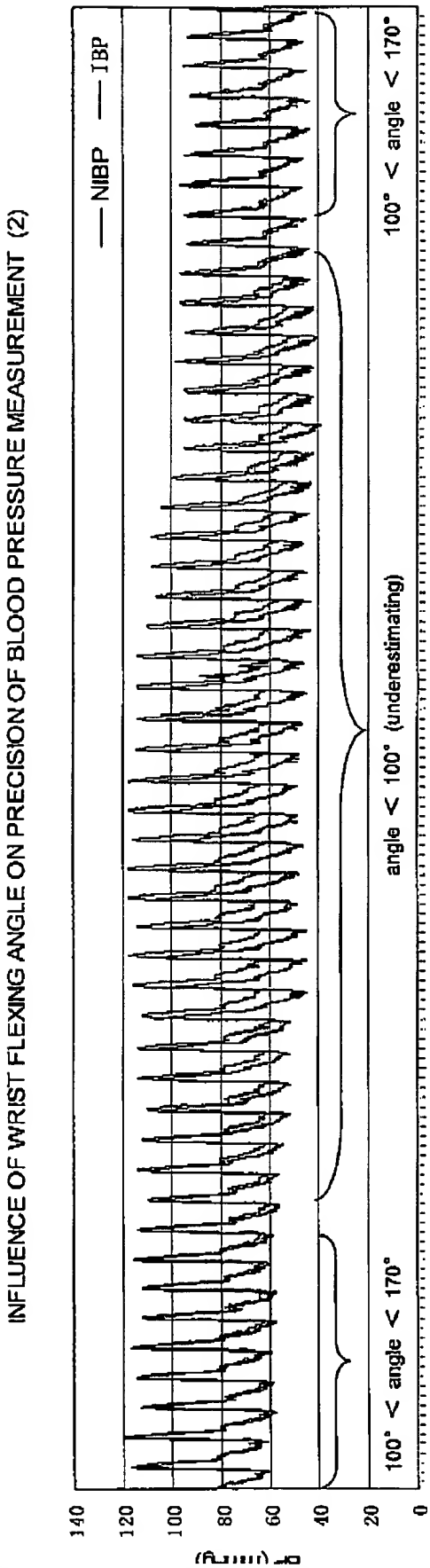
wrist flexing angle < 100°

(WP181546;1)



APPENDIX B

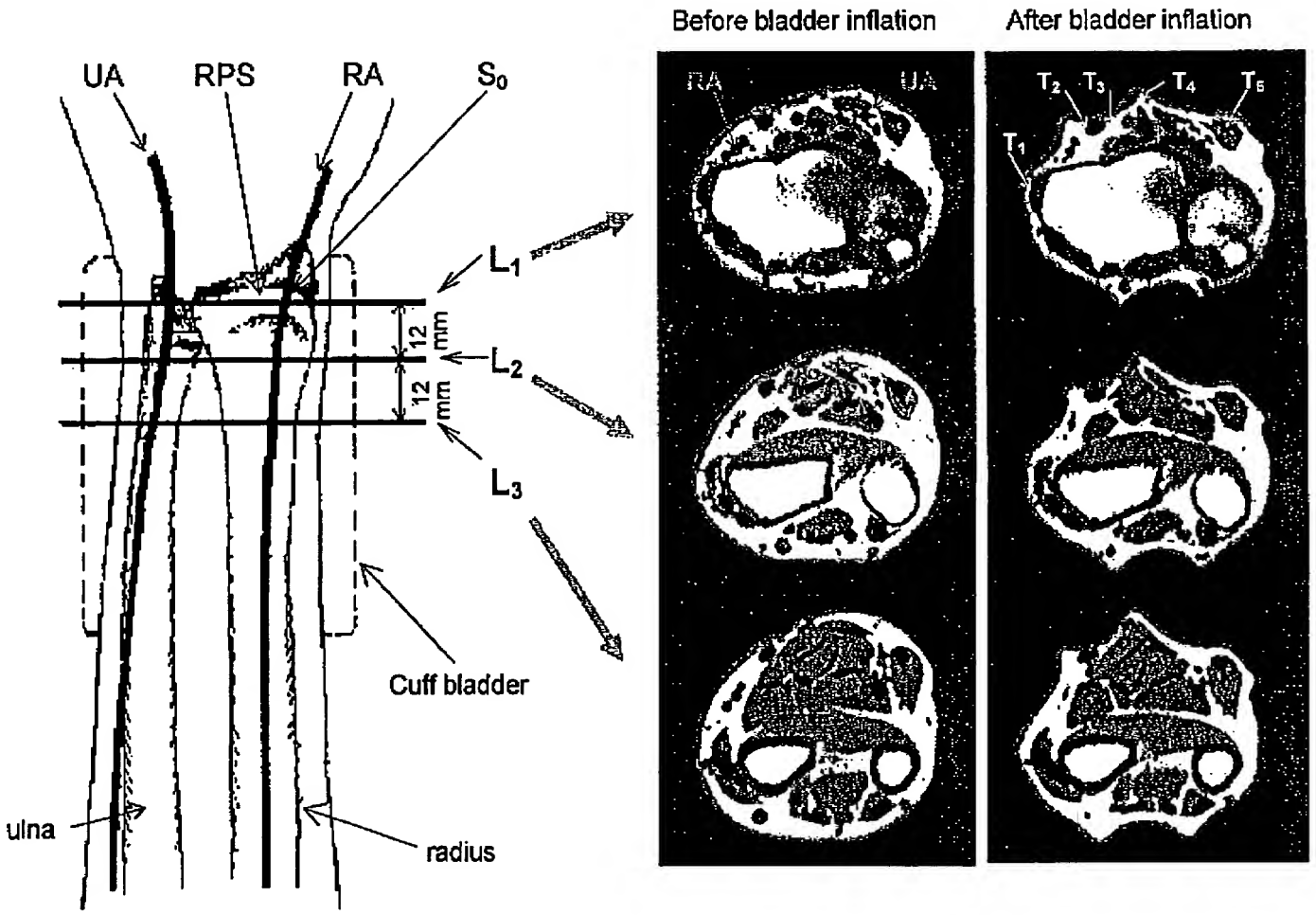

INFLUENCE OF WRIST FLEXING ANGLE ON PRECISION OF BLOOD PRESSURE MEASUREMENT (1)
NIBP
IBP
100° < angle < 170°
angle > 170° (overestimating)
100° < angle < 170°
Time
140
120
100
80
60
40
20
0


INFLUENCE OF WRIST FLEXING ANGLE ON PRECISION OF BLOOD PRESSURE MEASUREMENT (2)
NIBP
IBP
100° < angle < 170°
angle < 100° (underestimating)
100° < angle < 170°
Time
140
120
100
80
60
40
20
0

APPENDIX C_1

RESEARCH REPORT ON OPTIMAL MEASURING SITE (1)

MRI of wrist obtained at different level

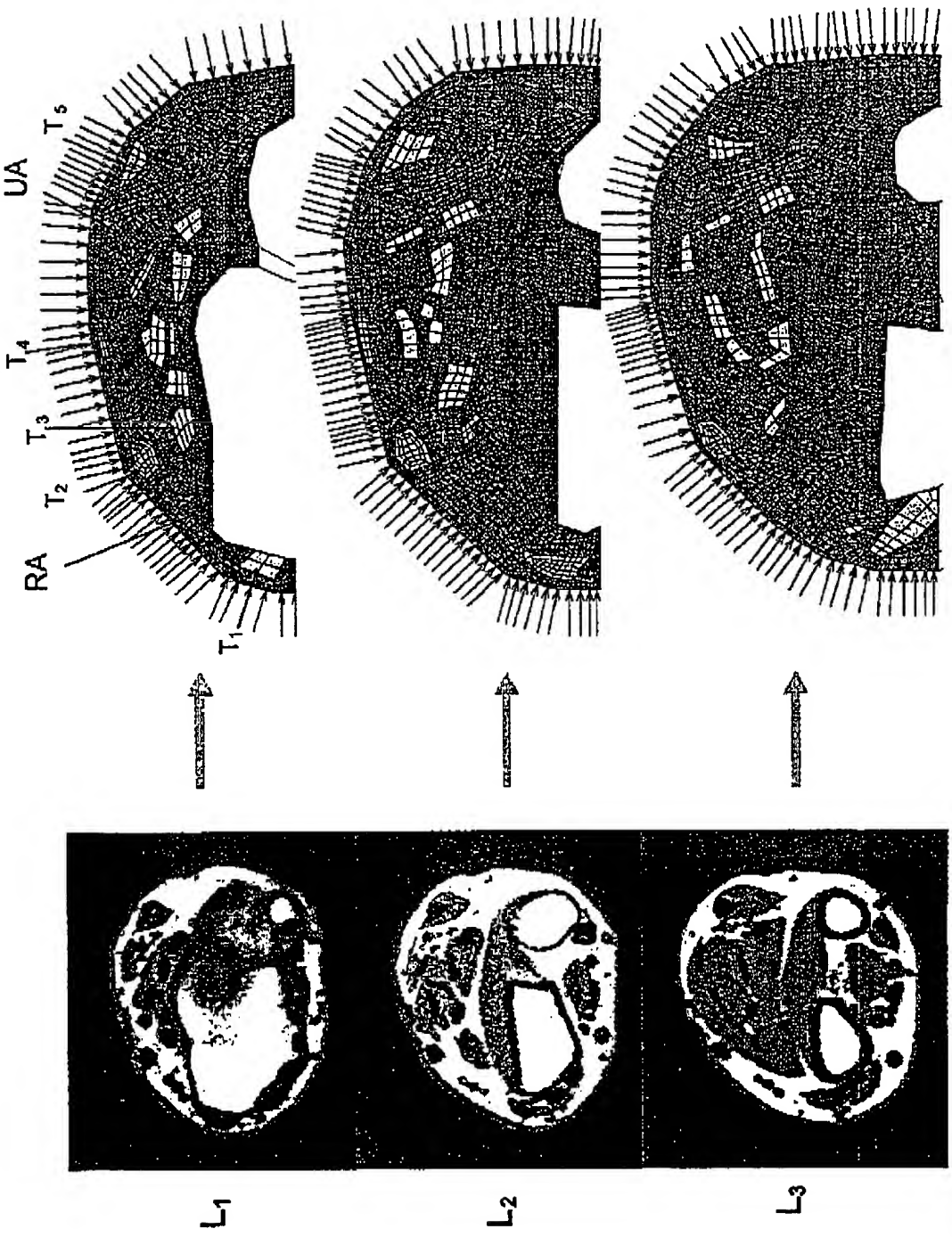


RPS: most protuberant spot on volar aspect of the radius S_0: crossing point of RA and RPS RA: radial artery UA; ulnar artery T1~T5: tendons

APPENDIX C_2

RESEARCH REPORT ON OPTIMAL MEASURING SITE (2)

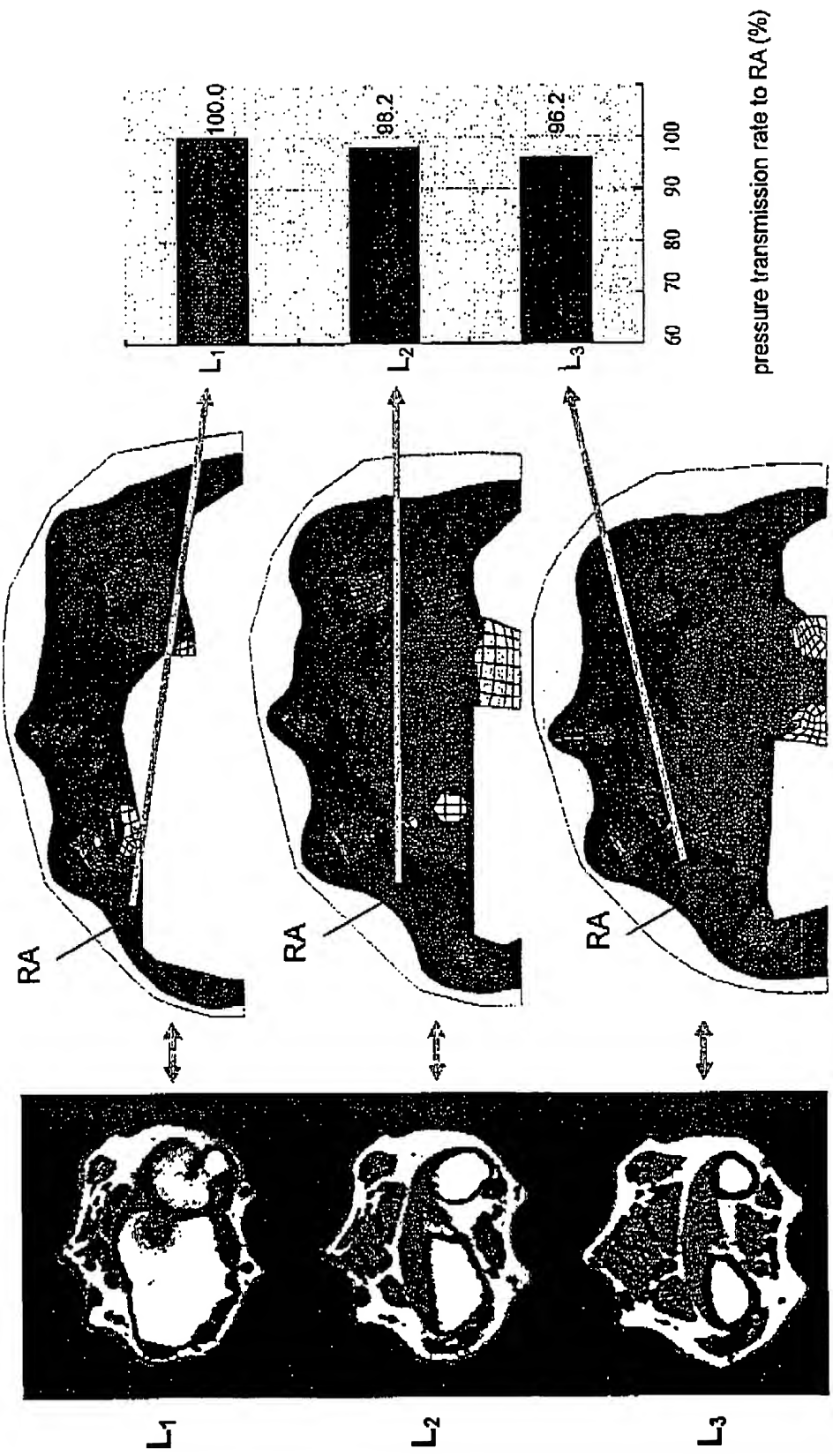
Finite element models of the wrist based on MRI



APPENDIX C_3

RESEARCH REPORT ON OPTIMAL MEASURING SITE (3)

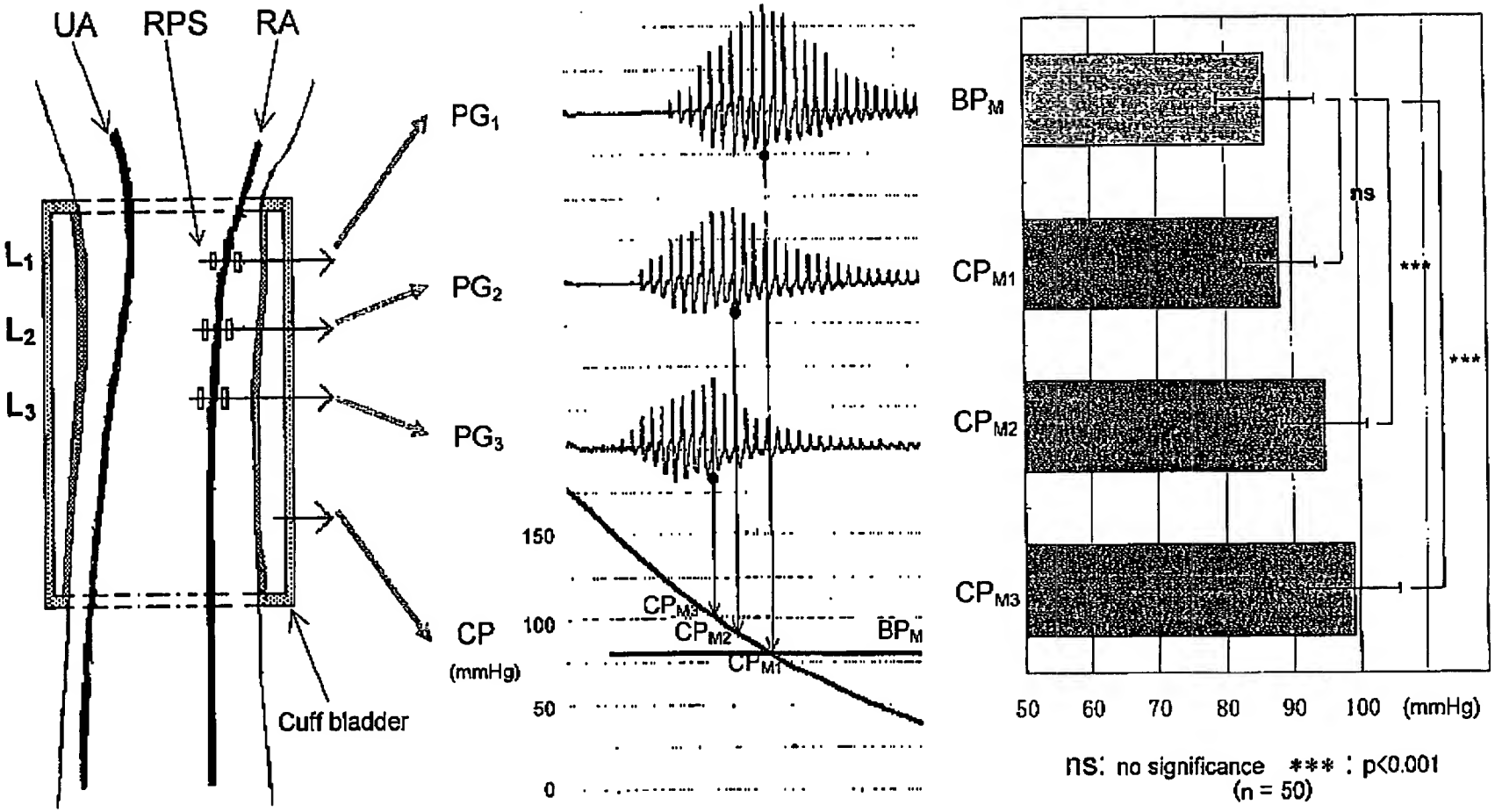
Stress maps and pressure transmission ratio to RA calculated in finite element models of the wrist



APPENDIX C_4

RESEARCH REPORT ON OPTIMAL MEASURING SITE (4)

Blood pressure measurement by using oscillometric method



CP: cuff pressure PG_1~PG_3 and CP_{M1}~CP_{M3}: plethysmogram and mean blood pressure measured at L_1, L_2 and L_3 BP_M: actual mean blood pressure